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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/319,541	08/19/1999	RAINER H. MULLER	62-659-50781	3247
20736	7590	09/09/2004	EXAMINER	
MANELLI DENISON & SELTER 2000 M STREET NW SUITE 700 WASHINGTON, DC 20036-3307			SHARAREH, SHAHNAM J	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/319,541	Applicant(s) MULLER, RAINER H.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9,25 and 31-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9,25 and 31-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/2002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendments filed on May 18, 2004 have been entered. Claims 9, 25, 31-56 are pending. Claims 37, 38, 44, and 51-53 are independent. Claims 37-38, 51-53 are directed to product. Claim 44 is directed to a process of making.

Any rejection that is not addressed in this Office Action is considered obviated in view of persuasive arguments.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include each section in order as described in the previous Office Action. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. Correction is requested.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 9, 31-35, 38, 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al US Patent 5,202,159.

Applicant's arguments with respect to claims 38 and 53 are not found persuasive, because they are not commensurate with the scope of the claims. Applicant argues that the instant claims require the excipient phase be coherent and that such property is achieved by dissolving the excipient in the liquid. Applicant asserts once the instant excipient of Chen is suspended in the liquid; it would form an incoherent excipient

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phase which is different from the claimed invention. (see Arguments at page 10, 3rd para.).

In response, Examiner first ascertains the scope of the instant claims. The instant product claims appear to be drafted as "product by process" claims. Accordingly, products by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113). "Even though product - by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

The instant claims also contain various functional. Nevertheless, the scope and the patentability of instant product claims are assessed based on their components and their physical characteristics. Applicant has not provided any evidence to show how presence of the same components leads to different final products when the patentability of the product is based on the products of prior art. Once the same components are present in the product, they final product inherently possess the same function and characteristics, regardless of their process of making. Therefore, the scopes of the instantly claimed products are not limited to the process steps for their production. Thus, claims stand rejected for the reasons of record.

Applicant argues that Chen's particles contain an incoherent excipient phase because Chen describes the dissolution of diclofenac in water, adding lactose and a

non-soluble polymer in the same solution and then spray drying such solution.

(Arguments at page 10, para.4). In response, Examiner states that the instant claims do not exclude components and products of Chen. Thus, the functional characteristics of the final product are inherently anticipated by the compositions of Chen.

Chen uses lactose as the excipient. The instant claims do not exclude lactose as the instant excipient. In fact, instant claim 40 and instant specification at page 22, line 20 describes the instant recitation of "excipients" to encompass lactose.

Chen uses diclofenac sodium. Page 15, line 26 of the instant specification embraces diclofenac as an instantly claimed active substance.

Chen uses Eudragit type polymers. The instant claims do not exclude such polymers. In fact, at page 20, line 28 of the instant specification; Eudragit type polymers are described to fall within the scope of the instant polymers.

Further, Chen even uses water as its liquid. The instant claims do not exclude water as the instant liquid. In fact at page 23, line 30 of the instant specification; water is described to fall within the scope of the instant liquid of claim 38 and 53.

Therefore, all components of the instant claims are present in Chen.. Moreover, Chen employs spray drying to prepare his compositions. Since compositions of Chen comprise the same components, which are used the same way, for the same purpose, to provide the same utility as the instantly claimed products; they must be the same as the instantly claimed products. Applicant has not provided any evidence to show otherwise. Thus, claims stand rejected.

Further, Applicant's argument that excipient of Chen is suspended is not persuasive, because dissolution is also a function of the concentration of a solute and the solvent. Applicant has not provided any evidence that no excipients particles are dissolved in the liquid of Chen.

Finally, the fact that Chen uses a binder to form a tablet at its final stage is not relevant to patentability of the instantly claimed spray dried particles. Applicant specifically argues that the instant claims require "the matrix material-containing compound is directly compressible into larger units of tablets without requiring binders." (see Arguments at page 10-12).

In response, Examiner replies that such claim is merely an ability of the claimed particles. Thus, it is not viewed as a positive limitation, rather a capability of the instant particles to provide the recited function. Aside from the fact that Chen's discloses all components of the instant claims, Chen specifically recites that his particles possess a compressibility index of at least 50%. Examiner relies on this teaching to show that Chen's final product are compressible within the scope of the instant claims. Applicant has not provided any evidence showing that such compressibility index indeed does not inherently provide the same function instantly recited. Thus, Applicant has not met the burden of proof.

Examiner has set forth that all components described in Chen is within the scope of the instant claims and the process steps are substantially the same, thus, all functional limitations of the claimed particles are also inherently anticipated.

Claims 9, 25, 31-43, 51-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Takada et al US Patent 5,561,990.

Applicant's arguments with respect to the instant rejection have been fully considered but are not persuasive, because they are not commensurate with the scope of the pending claim. Again, the claimed products do not exclude the products of Takada. Similarly, the instant methods do not exclude the methods described by Takada.

Applicant first argues that the compounds of the invention have a different structure as shown in Figure 4 of the present application. (see Arguments at page 13, 5th para.). In response, Examiner states that limiting claims by reading material from the specification to narrow the scope of the claims is improper. Since, the scope of the pending claims do not exclude the compositions of Takada, they are anticipated.

Applicant argues that the claimed formulation has an ability to be compressed without the use of a binder. (see Arguments at page 13, 6th para.) In response, Examiner states that such recitation is not viewed to be a positive limitation in a patentable sense, rather merely the ability to perform the recited function. Since Takada' microparticles comprise all elements of the instant claims, they are viewed to inherently be capable of performing the argued function.

Applicant also argues that the process steps of Takada are different from the instantly claimed process steps. In response, Examiner states that first of all the instant claims product claims, and not directed to the process that they are produced. Second, contrary to Applicant's position at page 14 of the Applicant's Arguments, Examiner

states that the fact that Takada used an emulsifier to formulate a emulsion is indicative of the fact that the polymer was insoluble in the spraying liquid.

Furthermore, there is no evidence on the record that spray drying the emulsion of Takada would not create the structure of the instant products, because emulsions are a dispersion of two immiscible systems which can be separated during a drying or spray drying process. Since, Takada's particles contain all elements of the instant claims and are prepared by spray drying methods. They inherently meet all functional characteristics of the instant particles.

Claim Rejections - 35 USC § 103

Claims 9, 25, 31-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '518 in view of Takada et al US Patent 5,561,990.

Applicant's arguments with respect to this rejection have been fully considered but are not persuasive.

Applicant primarily argues that the claimed invention exhibit the unexpected property of being directly compressible into firm tablets without the use of binder. (see page 18, para. 2nd and 6th). In response, Examiner states that none of the claims are positively limited to such features; thus, Applicant's arguments are moot because they are essentially directed to non-claimed limitation.

JP '518 teaches spray drying a suspension containing polymers such as pvp, cellulose derivatives, and/or lactose. The solvent system used in JP '518 is water. All such components fall within the scope of the instantly employed excipient, polymer and liquid. JP '518 clearly shows that prior to spray drying, the final mixture of drug, polymer

and excipient can be in the form of a suspension or solution depending on the nature of the components. Such characteristics thus are a matter of design choice and well within the level of ordinary skill in the art. Takada teaches that such polymeric moieties are successfully used in preparing microparticles possessing prolong release activity. (col 6, lines 20-38). Takada also characterizes PVAs and acrylic acid polymers as art equivalents (see col 62-67).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute PVP of JP '518 with acrylic or fatty acid polymeric moieties of Takada, because the ordinary artisan would have had a reasonable expectation of success in improve prolong release properties of JP particles.

Applicant has not provided any evidence that the formulations of prior art do not possess the instantly claimed functional characteristics. Neither has applicant provided any unexpected results. Thus, claims stand rejected for the reasons of record.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SHENGJUN WANG
PRIMARY EXAMINER